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08/231,565	04/22/94	KAWAKAMI	20284151

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EXAMINER	
ART UNIT 1806	PAPER NUMBER D
09/19/96	

DATE MAILED:

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

# Office Action Summary

Application No.  
**08/231,565**

Applicant(s)  
**Kawakami et al**

Examiner  
**Sheela J. Huff**

Group Art Unit  
**1806**



☒ Responsive to communication(s) filed on Aug 5, 1996

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-57 is/are pending in the application.

Of the above, claim(s) 6-55 is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-5, 56, and 57 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 6,8

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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## DETAILED ACTION

### *Election/Restriction*

1. Applicant's election with traverse of Group I, claims 1-5, in Paper No. 12 is acknowledged. The traversal is on the ground(s) that Groups II, III and IV are assigned to class 530 and Groups III, V, VI and VII are assigned to Class 435 and therefore searching Groups II-IV together does not result in an unduly burdensome search and that searching Groups III and V-VII together does not result in an unduly burdensome search. Applicant further argues that the nucleic acid sequences may be used in the inventions of Group II and V-VII. This is not found persuasive because the subclasses of Groups II and III in Class 530 are different and peptides are not antibodies. Even though the subclass of Groups II and IV are the same gp100 and MART-1 is structurally different proteins. The subclasses for Groups II, V and VI are different. Even though the subclass for Groups V and VII are the same these inventions are distinct because they relate to different methods. Group I is distinct from the remaining groups for the reasons of recited in Paper no. 11, mailed 7/3/96.

The requirement is still deemed proper and is therefore made FINAL.

2. The election requirement between gp100 and MART-1 of claims 56-57 is withdrawn and therefore claims 1-5 and 56-57 are currently under consideration.

Claims 6-55 are withdrawn from consideration.

### *Information Disclosure Statement*

3. The IDS filed on 10/21/94 and 11/2/95 have been considered. Copies of the initialed PTO-1449 are enclosed.

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**Claim Objections**

4. Claim 57 is objected to because of the following informalities: Because applicant is claiming a recombinant expression vector, applicant should specify that the nucleic acid sequence is linked to an expression control sequence. Appropriate correction is required.

*61, 64-65*  
**Claim Rejections - 35 USC § 112**

5. Claims ~~1-5~~ and ~~56-57~~ are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for cDNA sequences of MART-1 (specifically SEQ. ID. No.1) and gp100, does not reasonably provide enablement for chromosomes, allelic variations, homologs, variants or muteins thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claim 1 reads on chromosomes and applicant has not enabled the entire chromosome.

Applicant has not defined allelic variations, homologs or variants nor has applicant provided any examples of what is encompassed by this terminology. Are nucleotides changed, replaced, deleted or inserted into the cDNA sequences? Which nucleotides are changed, replaced or delete?

Claim 56 reads on muteins and variants. As discussed in the last paragraph, this terminology has not been defined.

Claim 56 uses the terminology "comprising". This means that the peptide can have anything (such as organic groups, inorganic groups, labels etc) attached to it. How can a nucleic acid sequence be made to inorganic groups, organic groups, etc? Which peptides of MART-1 or gp100 is applicant referring to. These are large proteins and the number of possible peptides "comprising at least about 8 contiguous amino acids" is enormous. Do these nucleic acid sequences encode a peptide with a specific function? If so, what is the function?

In view of the above, undue experimentation would be required by one skilled in the art to make and use the claimed invention.

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6. Claims 1-5 and 56-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 1 and 56 are vague and indefinite because of the abbreviation MART-1. The definition of MART-1 should be specifically recited in the claims.

b. Claims 3-5 are vague and indefinite because the terminologies allelic variations, homologs or variants have not been defined.

c. In claim 56, line 5, it is unclear as to why "#" is present before gp100.

d. In claim 56, line 3, the terminology "being derived from" is vague and indefinite. Derived how, where?

e. In claim 56, line 6, what does "being reactive to" mean? Does this mean --binds--? If so, binds where?

f. In claim 57, line 1, it is unclear as to why there is a "?" after comprising.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

8. Claim 1 is rejected under 35 U.S.C. 102(a) as being anticipated by Maresh et al DNA and Cell Biology vol. 13(2) p. 87 (2/94) or Gaugler et al J. Exp. Med. vol. 179 p. 921 (3/94).

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Maresh et al disclose a cDNA that encodes for melanoma antigen ME20 (p. 87, second column and Figure 2).

Gaugler et al disclose the cDNA sequences MAGE-1 and MAGE-3 (fig. 5) which codes for antigens recognized on a melanoma by T-lymphocytes.

9. Claims 1 and 56-57 are rejected under 35 U.S.C. 102(a) as being anticipated by Adema et al Am J. Pathol vol. 143 p. 1579 (12/93).

This reference discloses the cDNA for gp100 and an expression vector containing said cDNA (p. 1581 columns 1-2).

~~10.~~ Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Traversari et al J. Exp. Med vol. 176 p. 1453 (1992).

This reference discloses that the genes of MAGE 1-6 are known (Figure 4).

11. Claims 1 and 56 are rejected under 35 U.S.C. 102(b) as being anticipated by Kwon et al PNAS vol. 88 p. 9228 (1991).

This reference discloses the cDNA for Pmel is known (page 9228-second column, line 7 under "Isolation of cDNA Clones" and the deduced amino acid sequence of Pmel(Fig. 1). The deduced amino acid sequence of Pmel is very similar to gp100.

***Claim Rejections - 35 USC § 103***

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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13. The factual inquiries set forth in *Graham v. John Deere Co.*, 148 USPQ 459, that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or unobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 56-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO92/21767 in view of Kwon et al PNAS vol. 88 p. 9228 (1991).

WO 92/21767 discloses Seq ID NO. 1 on page 20 which corresponds to amino acid residues 25-53 of gp100 (aka Pmel). Seq ID No. 1 reads on "at least about 8 contiguous amino acids".

This reference does not disclose a cDNA sequence encoded by the peptide or the use of the cDNA in an expression vector.

However, Kwon et al disclose that the cDNA of Pmel is known.

Because the cDNA sequence is known, it would have been obvious to one of ordinary skill in the art at the time of the invention to isolate a cDNA sequence which encodes a peptide corresponding to Seq ID No. 1. The use of cDNA sequences in expression vectors to express more protein is routine in the art.

### **Conclusion**

15. PNAS, vol. 91 p. 3515 is not prior art because it was published on 4/26/94, which is after the filing date of the instant application.

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16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheela J. Huff whose telephone number is (703) 305-7866. The examiner can normally be reached on Monday-Thursday from 6:30am to 3:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marian Knode, can be reached on (703) 308-4311. The FAX phone number for this Group is (703)308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Sheela J. Huff  
September 4, 1996

*Toni R. Scheiner*

TONI R. SCHEINER  
PRIMARY EXAMINER  
GROUP 1800